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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/937,062	01/29/2002	Katsuhiro Shirakawa	019952-167	6296
21839	7590	06/09/2004	EXAMINER	
BURNS DOANE SWECKER & MATHIS L L P POST OFFICE BOX 1404 ALEXANDRIA, VA 22313-1404			BOCKELMAN, MARK	
			ART UNIT	PAPER NUMBER
			3762	

DATE MAILED: 06/09/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	09/937,062	SHIRAKAWA ET AL.	
	<b>Examiner</b>	<b>Art Unit</b>	
	Mark W Bockelman	3762	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) Responsive to communication(s) filed on 17 March 2004.
- 2a) This action is FINAL.                    2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) Claim(s) 1-8,10-15 and 17 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) Claim(s) \_\_\_\_\_ is/are allowed.
- 6) Claim(s) 1-8,10-15 and 17 is/are rejected.
- 7) Claim(s) \_\_\_\_\_ is/are objected to.
- 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
  - a) All    b) Some \* c) None of:
    1. Certified copies of the priority documents have been received.
    2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
    3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |   |   |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)                     |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                    | Paper No(s)/Mail Date. _____  |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____. | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
|   | 6) <input type="checkbox"/> Other: _____.                                   |

**DETAILED ACTION*****Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-5, 8, 10 and 17 are rejected under 35 U.S.C. 102(e) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Verness et al USPN 6,285,910

Verness et al shows an implantable electrode lead (figure 1) with a distal end electrode 16 and a connecting terminal 36 with a lead body there between As stated in column 3 line 35 to column 4 line 47 of Verness et al two conductors 116 and 118 may provide a redundant connection between the connector pin and the distal end electrode. It is the examiner's point of view that at least figure 4 of

Verness et al show a helical parallel coil of a plurality of wires. While the pitch (or winding number) of wire 118 differs from that of wire(s) 116, they nevertheless form a helical parallel coil that is parallel. It is the applicant's position that figure 4 does not show such, with no particular reason stated, but in the event that applicant, upon further explanation, argues that it is something different (i.e. requires the same number of loops per length), the examiner considers such an arrangement to be an obvious design choice depending on how the catheter lead is desired to be reinforced. Although the reference does not explicitly state that wires 118 and 116 have different properties namely resistance and/or other mechanical (e.g material) properties, such is strongly inferred and is considered anticipatory or otherwise obvious. Verness states that while multifilar wire 116 is of a conventional type of wire, wire 118 is constructed of a strong fatigue resistant material such as MP35N which may resist breaking. Therefore the examiner concludes that one of ordinary skill in the art would consider this a teaching of using different materials for wires 188 and 116, or would otherwise consider it obvious.

Similarly, Verness et al states in column 4 beginning at line 15, that the redundant coupling of wire 118 and 116 between the electrode and the pin will result in a relatively small impedance change, but in the event wire 116 is broken, a large impedance change will manifest. To those familiar with basic circuitry, one would immediately realize that this can only be done by providing wires of substantially different resistivity wherein the effective resistance for the parallel wires would satisfy:

$R_1 \gg R_2$

And  $R_{\text{parallel}} = \frac{R_1 R_2}{R_1 + R_2}$

For an  $R_1$  10 times greater than  $R_2$ ,  $R_{\text{parallel}}$  approximately equals  $R_2$

Since this is the only possible way the examiner is aware of to meet the conditions specified by Verness and the examiner again concludes that the use of two different materials of different resistivities is taught, or would have otherwise been apparent to one of ordinary skill in the art.

Dependent claims 4 and 8 when read into claim 3 still provide a choice between a single conductor and a composite conductor with Verness showing a single layer conductor.

Claims 4, 6-8 are rejected under 35 U.S.C. 103(a) as being unpatentable over Verness et al USPN 6,285,910 in view of Shirakawa EP 1005879. While Verness does not teach applicant's two layered wire or applicant's specific resistivity range such are conventional as demonstrated by Shirakawa.

Claims 12-13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Verness et al USPN 6,285,910. While Verness does not get into the details of his detection system, it would have been obvious to one of ordinary skill in the art to compare the either the, current, voltage, resistance and or impedance of the lead to a preset value so as to determine when the impedance of the Verness lead rises indicating lead breakage. It is an obvious design choice to select the

preset value to be either a maximum or minimum depending on which of the indicative parameters is to be compared.

Claims 11, 14-15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Verness et al USPN 6,285,910 in view of Meyerson et al. USPN 5,179,947. Applicant differs from Verness in reciting a body motion sensor in the form of an accelerometer as well as a storage means for storing measured data. Such inclusions are considered conventional in the art with the examiner citing Meyerson as showing the use of an accelerometer.

### ***Response to Arguments***

Applicant's arguments filed 3-17-2004 have been fully considered but they are not persuasive. Applicant argues that Verness et al does not teach a helical coil of the wires with two different resistivities which the examiner disagrees. Webster's dictionary considers helical in its broadest term to mean spiral, which is clearly taught in the Verness disclosure that accompanies figure 4. The two wrapped spiraling wires are clearly parallel as well. Even if not consider to meet the claim language, the mere providing of wire 18 as an attached member of the wire 116 would constitute a mere design choice which would add nothing to the operation and function of the redundant connection taught by Verness et al.

### ***Conclusion***

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL.**

See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mark W Bockelman whose telephone number is (703)-308-2112. The examiner can normally be reached on Monday - Thursday 10-8:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela Sykes can be reached on (703) 308-5181. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

MWB



MARK BOCKELMAN  
PRIMARY EXAMINER

June 6, 2004